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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/647,619	08/25/2003	Dennis A. Boismier	1001.1689101	2861

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EXAMINER

WYSZOMIERSKI, GEORGE P

ART UNIT PAPER NUMBER

1742

DATE MAILED: 12/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/647,619

Applicant(s)

BOISMIER ET AL.

Examiner

George P. Wyszomierski

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 1-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 23-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/3/03, 2/1/05</u> | 6) <input type="checkbox"/> Other: ____  |

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1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-22, drawn to a method, classified in class 148, subclass 563.
- II. Claims 23-27, drawn to a product, classified in class 623, subclass various.

2. The inventions are distinct, each from the other because:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process as claimed can be used to make a materially different product, such as a temperature activated switch.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their different classification and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

3. During a telephone conversation with Glenn Seager on November 29, 2005 a provisional election was made without traverse to prosecute the invention of Group II, claims 23-27. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-22 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

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or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 23, 24, 26 and 27 are rejected under 35 U.S.C. 102(a) as being anticipated by Eder et al. (U.S. Patent 6,585,753).

Claims 23, 24, 26 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Sagae et al. (Reissue patent 36,628) or McNamara et al. (U.S. patent 6,254,550).

Claims 23, 24, 26 and 27 are rejected under 35 U.S.C. 102(e) as being anticipated by Davis et al. (PG Pub. 2004/0111044).

Each of Eder, Sagae, McNamara and Davis discloses medical devices in the form of wire loops and core wires for use as stents, made of a superelastic material (generally nitinol),

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and including at least one portion which has been heat treated to have a higher flexibility or workability. Thus, each of Eder et al., Sagae et al., McNamara et al., and Davis et al. are held to fully disclose all aspects of the presently claimed invention.

6. Claims 23 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Sachdeva et al. (U.S. Patent 5,683,245).

Sachdeva discloses orthodontic archwires made of Ni-Ti alloys and including portions which have been differentially heat treated to result in different modulus of elasticity in different portions of the material. Note especially the paragraph overlapping columns 4-5 of Sachdeva. Thus, all aspects of the claimed invention are held to be fully disclosed by Sachdeva et al.

7. Claims 23, 24, 25 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Kleshinski (U.S. Patent 5,776,162).

Kleshinski discloses a material for use as a filter implanted in a human body in the form of a stent, and made of Nitinol wire in wire loop form which has been differentially heat treated to result in localized portions more pliable than other portions. Thus, all aspects of the claimed invention are held to be fully disclosed by Kleshinski.

8. Claims 23-26 are rejected under 35 U.S.C. 102(b) as being anticipated by DiCarlo et al.

DiCarlo discloses stents which may include wire loops or filter-shaped arrangements (see Figs. 8A and 8B of DiCarlo), made of Nitinol, and including portions which have been differentially heat treated to result in portions having higher ductility than other portions; see

DiCarlo column 3, lines 45-65. Thus, all aspects of the claimed invention are held to be fully met by the disclosure of DiCarlo et al.

9. Claims 23 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0395098.

The '098 reference discloses catheter guide wires including a core wire made of Ti-Ni alloy and including portions which have been heat treated to provide greater elasticity in those portions than the non heat-treated portions. Thus, all aspects of the claimed invention are held to be fully met by the EP '098 disclosure.

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sachdeva et al., Kleshinski, or DiCarlo et al.

The Sachdeva, Kleshinski and DiCarlo patents, described supra, do not use the term "core wire" in their respective disclosures. However, it is unclear what the precise definition would be of the term "core wire", and the devices disclosed in the prior art appear to be of a physical configuration similar to that identified as a core wire in the present specification, e.g. Fig. 9 of the specification. Based on the substantial similarity in both material used and physical configuration, a prima facie case of obviousness is established between the wires disclosed by Sachdeva et al., Kleshinski or DiCarlo et al. and the presently claimed invention.

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12. Claims 24 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0395098.


The EP '098 disclosure, described in item no. 9 supra, does not use the terms "stent" or "core wire". However, note that the purpose of the '098 devices is for use as a catheter guide wire, to guide a catheter through cavities such as blood vessels within a body. Given this disclosure of '098, no patentable distinction is seen between the devices as disclosed therein, and devices defined as a "stent" or "core wire" in the instant claims. Thus, the EP '098 document is held to create a prima facie case of obviousness of the presently claimed invention.

13. The remainder of the art cited on the attached PTO-892 and 1449 forms is of interest. This art is held to be no more relevant to the claimed invention than the art as applied in the rejections, supra.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to George Wyszomierski whose telephone number is (571) 272-1252. The examiner can normally be reached on Monday thru Friday from 8:00 a.m. to 4:30 p.m. Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Roy King, can be reached on (571) 272-1244. All patent application related correspondence transmitted by facsimile must be directed to the new central facsimile number, (571)-273-8300. This new Central FAX Number is the result of relocating the Central FAX server to the Office's Alexandria, Virginia campus.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
GEORGE WYSZOMIERSKI  
PRIMARY EXAMINER  
GROUP 1742

GPW

December 5, 2005